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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,303	04/09/2004	Rino Rappuoli	20480.019	3584

27476 7590 10/17/2006

NOVARTIS VACCINES AND DIAGNOSTICS INC.
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EXAMINER	
MOSHER, MARY	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,303	RAPPUOLI ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-120* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-120* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Please note, election of species is further required for several of these groups.

1. Claims 1-8, 22 (in part), 23, 24, 25-28(in part), 90-98, 102-104, 114-118 (in part), drawn to polypeptide, classified in class 530, subclass 221.1.
2. Claims 9-12, 59-76, 85-89, 99-101, 105-109, drawn to nucleic acid, classified in class 536, subclass 23.72.
3. Claims 13-17, drawn to antibody, classified in class 530, subclass 389.4.
4. Claims 18-21, drawn to immunoassays, classified in class 435, subclass 5.
5. Claims 22 (in part), 25-28 (in part), 29-37, 114-118 (in part), drawn to whole or split virus vaccine composition and method, classified in class 424, subclass 221.1.
6. Claims 38-41, drawn to virus inactivation method, classified in class 435, subclass 236.
7. Claims 42(in part)-49, drawn to virus culture method, classified in class 435, subclass 235.1.
8. Claims 42 (in part), 50-58, drawn to virus purification method, classified in class 435, subclass 239.
9. Claims 77-83, 119, 120 drawn to body-treating method, classified in class 514, subclass 1.

10. Claim 84, drawn to drug screening method using infected cells, classified in class 435, subclass 32.

11. Claims 110-113, drawn to drug screening method using isolated enzyme, classified in class 435, subclass 23.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1, 2, and 3 are directed to related biomolecules. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different modes of operation, functions, and effects, and do not overlap in scope. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions 1 and 5 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the whole virus or split virus vaccine relies upon the characteristics of all of the subunits together, not on any one

polypeptide in isolation. The subcombination has separate utility such as for inducing subunit-specific polyclonal antibodies.

> The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions 1 and 3 are related to invention 4 as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case either the antibody or the antigen can be used in a materially different body-treating method, such as active or passive immunization.

Inventions 5 and 6 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the inactivated virus vaccine can be made by a materially different method such as irradiation.

Inventions 6, 7, and 8 are related as process subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination 6 (inactivation) has separate utility such as inactivating unpurified virus. Subcombination 7 (culturing) is usable separately from the particular inactivation method of group 6 or the particular purification method of group 8. Similarly, subcombination 8 (purification) can be separately from the particular inactivation method of group 6 or the particular culture method of group 7. See MPEP § 806.05(d).

> The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Inventions 9 and 10 are unrelated to each other and unrelated to the other inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the treatment method of group 9 is not disclosed as capable of use together with any of the claimed products, and has different mode of operation and effects compared with the other claimed methods. Likewise, the group 10 screening process using infected cells does not use

any of the isolated products claimed, and has materially different mode of operation and effects from the other methods claimed.

Inventions 1 and 11 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the isolated enzyme can be used as an antigen in a immunization method or in an immunoassay.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Election of Species

Group 1 contains claims generic to a multitude of disclosed patentably distinct species. Any two polypeptides which do not share a substantial degree of sequence identity are patentably distinct species. For example, each viral subunit is patentably distinct from the other viral subunits. Furthermore, a small oligopeptide can be patentably distinct from a larger polypeptide which comprises the oligo sequence, because nothing in the large sequence points particularly to the specific boundaries of a small segment, and nothing in the sequence of a small oligopeptide suggests the structure or characteristics of the rest of the large protein. The products are patentably

distinct from each other, because each has different structural, functional, and immunological characteristics that are not predictable from the other products.

Applicant is required under 35 U.S.C. 121 to elect **a single disclosed species of polypeptide**, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

> Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Groups 3 and 4 are subject to the same election of species as group 1. That is, for group 3, applicant is required to elect one species of antibody, defined according to the species of polypeptide to which the antibody is directed; for group 4, applicant is require to elect one species of antigen which is detected or used in the immunoassay. The species of antibody and immunoassay are distinct from each other for the same reason that the antigen (polypeptide) species are distinct from each other.

Group 2 also contains claims generic to a multitude of disclosed patentably distinct species. Any two nucleic acids which do not share a substantial degree of sequence identity are patentably distinct species, for reasons similar to those given for polypeptides. In addition, group 2 includes functionally distinct categories of nucleic acids, such as coding sequences, primer pairs, and inhibitory double-stranded RNAs.

Applicant is required under 35 U.S.C. 121 to elect **a single disclosed species of coding sequence, OR a single disclosed species of oligonucleotide, OR a single disclosed pair of primers, OR a single disclosed species of inhibitory dsRNA** , even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

> Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Group 5 contains claims generic to the following disclosed patentably distinct species of vaccine:

a. Split, killed, or inactivated by detergent

b. killed or inactivated by formaldehyde or formalin

c. killed or inactivated by beta-propriolactone

d. killed or inactivated by UV light or gamma irradiation

e. killed or inactivated by methylene blue

f. killed or inactivated with psoralen

g. killed or inactivated with carboxyfullerene

h. killed or inactivated with binary ethylamine or acetyl ethlyeneimine.

The species are independent or distinct because each causes different kinds of structural modification to the virion. For example, formaldehyde makes different adducts than psoralen, and one cannot a priori predict whether any two products have immunogenic effects similar to each other or similar to the unmodified virus.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

> Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10/11/06

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER